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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,251	11/01/2001	Robert K. Naviaux	UCSD1140-1	9760
<div>7590 07/09/2009</div> LISA A. HAILE, PH.D. GRAY CARY WARE & FREIDENRICH LLP 4365 EXECUTIVE DRIVE, STE 1100 SAN DIEGO, CA 92121-2133			<div>EXAMINER</div> KWON, BRIAN YONG S	
			<div>ART UNIT</div> 1614	<div>PAPER NUMBER</div>
			<div>MAIL DATE</div> 07/09/2009	<div>DELIVERY MODE</div> PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

09/889,251

**Applicant(s)**

NAVIAUX, ROBERT K.

**Examiner**

Brian-Yong S. Kwon

**Art Unit**

1614

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05/08/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 67,74-91,95-111 and 114-145 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 67,74-91,95-111 and 114-145 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date: \_\_\_\_\_

***Election/Restrictions***

***Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 67, 74-90, 111, 114-128 and 130-144 drawn to a method for a treatment of mitochondrial disorder comprising administering L isomer or D isomer of a keto tautomer or an enol tautomer of a compound represented by the Formula I or Formula IA.

Group II, claims 91 and 95-110, 129 and 145, drawn to reducing or eliminating one or more symptoms associated with a mitochondrial disorder comprising administering L isomer or D isomer of a keto tautomer or an enol tautomer of a compound represented by the Formula I or Formula IA.

The Inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical feature in both groups is L isomer or D isomer of a keto tautomer or an enol tautomer of a compound represented by the Formula I or Formula IA. This element cannot be a special technical feature because the element is shown in the prior art (Page et al., Proc. Natl. Acad. Sci. USA, Vol. 94, pp. 11601-11606; JP 53056690; USP 6258795; North et al., Journal of Virology, 1981, p. 987-

993; etc...). Therefore, Groups I and II do not share special technical feature with one another. As such, unity between the above Groups I and II is broken.

### *Species Election*

2. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

If applicant elects Group I or II invention, applicant is required under 35 USC 121 to elect a single disclosed species from following (a) or (b).

- (a). L isomer or D isomer of a keto tautomer or an enol tautomer of a compound represented by the Formula I or Formula IA mono-therapy.
- (b). L isomer or D isomer of a keto tautomer or an enol tautomer of a compound represented by the Formula I or Formula IA combination therapy with co-factors, vitamins or mixtures thereof.

If applicant selects Group I(a) or II(a), one specific compound from generic chemical structure of the compound represented by formula (I) or (IA), for example triacetyluridine, should be selected to be fully responsive.

If applicant selects Group I(b) or II(b), one specific compound from generic chemical structure of the compound represented by formula (I) or (IA) and "o-factors, vitamins, or mixtures of two more thereof", for example triacetyluridine and thiamine (B1) combination, should be selected to be fully responsive.

In addition, if applicant selects Group I, one specific species from different mitochondrial disorder, for example MARIAHS syndrome, should be selected to be fully responsive. The following is a list of different inflammatory disorders or diseases, e.g., multiple mitochondrial deletion syndrome, Leigh syndrome, 3-hydroxybutyric academia, pyruvate dehydrogenase deficiency, complex I deficiency, complex IV deficiency, MARIAHS syndrome....

In addition, if applicant selects Group II, one specific species from “one or more symptoms associated with a mitochondrial disorder” should be selected to be fully responsive.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian-Yong S. Kwon whose telephone number is 571-272-0581. The examiner can normally be reached on 9:00-5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian-Yong S Kwon/

Primary Examiner, Art Unit 1614